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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,646

01/13/2004

Tracee Eidenschink

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

04/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,646	<b>Applicant(s)</b> EIDENSCHINK ET AL.	
	<b>Examiner</b> Ryan J. Severson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15, 21, 22, 24-38 and 51-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 21, 22, 24-38 and 51-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/25/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 2, 5-9, 31-38 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974).** Cox discloses a catheter assembly with a balloon catheter (see figure 22) disposed within a rotatable sheath (350). The rotatable sheath has a guidewire housing (the guidewire can pass through any of the bores 368). However, the embodiment shown in figure 22 does not have end portions of the sheath that have a smaller inner diameter than the central portion. Attention is drawn to figure 8 of Cox, which shows a tubular member having a tapered end to present a less traumatic end to the hollow member that enhances the safe advancement of the tubular member in a vessel (see column 9, lines 20-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the ends of the sheath (350 shown in figure 22 of Cox) with tapered ends as in figure 8 to present atraumatic ends of the sheath for insertion and retraction in the blood vessel.

3. Regarding claims 31-38, Cox does not disclose the materials for the sheath as claimed. It would have been obvious to one having ordinary skill in the art to make the sheath of the claimed materials, since it has been held to be within the general skill of a

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worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

4. **Claims 3, 4, 15, 21, 22 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) as applied to claims 1 and 62 above, and further in view of Wilson et al. (6,165,195).** Cox does not disclose a stent disposed about the sheath and guidewire housing. Attention is drawn to Wilson et al., who teach the use of a stent disposed about a guidewire assembly (see figure 13D) and balloon to allow the stent to be placed at a point of a bifurcation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have disposed a stent about the guidewire housing and sheath of Cox in the manner taught by Wilson et al. to allow the balloon catheter to deliver a stent to a point of a vessel bifurcation.

5. **Claims 24-29 and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) in view of Wilson et al. (6,165,195) as applied to claim 15 above, and further in view of Healy et al. (5,670,161).** The combination of Cox and Wilson et al. does not disclose the stent has therapeutic coatings disposed thereon. Attention is drawn to Healy et al., who teach the use of various therapeutic coatings on a stent to speed healing at the site of deployment of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a therapeutic coating on the stent of the combination of Cox and Wilson et al. in the manner taught by Healy et al. to speed healing at the site of deployment of the stent.

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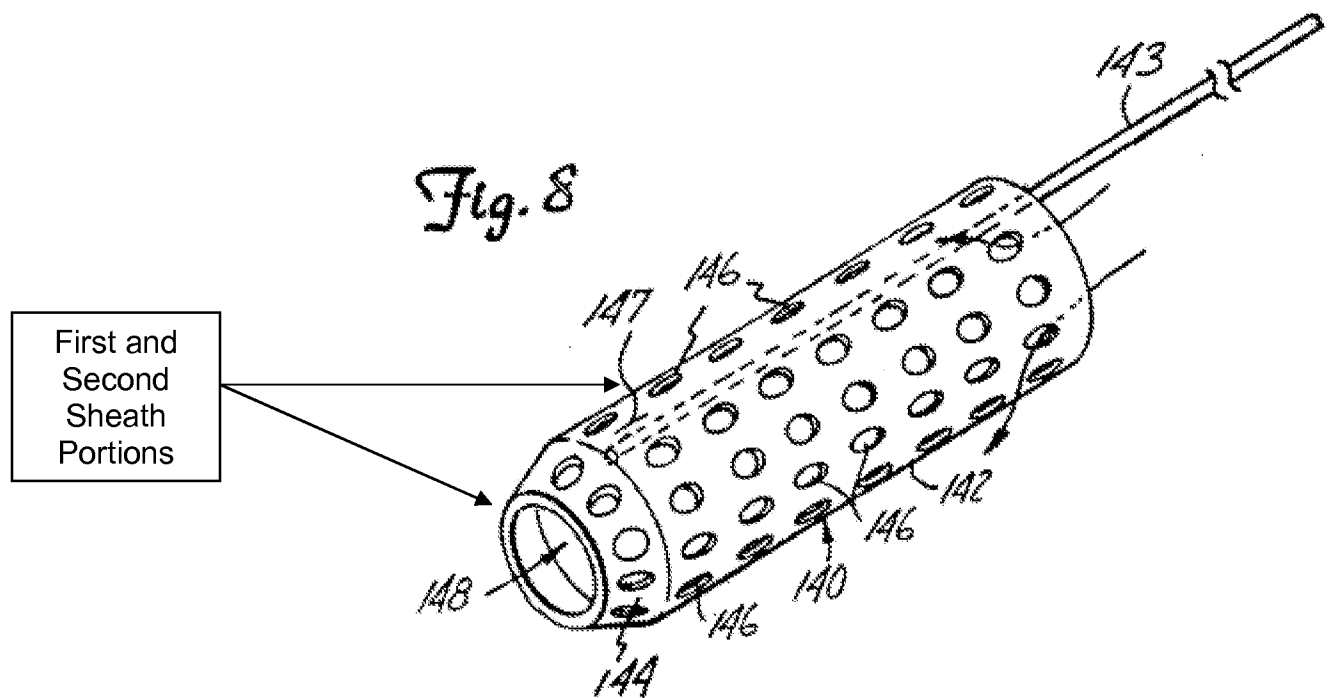
6. **Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) as applied to claim 1 above, and further in view of Lenker et al. (6,350,278).**

Cox does not disclose a lubricious coating positioned between the sheath and the shaft. Attention is drawn to Lenker et al., who teach a lubricious material applied between the catheter shaft and the sheath (see Column 9, Lines 58-64) to reduce the amount of friction between the two components. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricous coating between the sheath and the catheter shaft in the manner taught by Lenker et al. in the device of Cox to reduce the amount of friction between the two components.

#### ***Response to Arguments***

7. Applicant's arguments filed 17 December 2008 have been fully considered but they are not persuasive.

8. Applicant argues nothing about figures 22 and 8 and Cox show a rotatable sheath about a balloon and having the claimed first and second inner diameters. However, figure 22 of Cox clearly shows the sheath is disposed about the balloon. Further, the sheath is capable of being rotated about the balloon. Examiner can find no structure in the Cox device preventing such rotation from occurring. Further, figure 8 clearly shows an end of a tubular structure that is radially tapered. The annotated figure below clearly shows two exemplary locations where the inner diameters are shown to be different.



9. Further, figure 8 was not relied upon at any point to teach a “sheath rotatably disposed about a balloon.” Figure 8 is merely used to show tubular structures can have a radially tapered end section.

10. Applicant also argues that at no point in the office action was a “guidewire housing” cited. However, applicant’s attention is drawn to paragraph 6 in the previous rejection, and paragraph 2 above. Examiner notes that the actual guidewire has not been claimed, and the housing is interpreted as the area defined by the bores (368, see figure 22). A guidewire is capable of being passed through any of the bores.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./  
Examiner, Art Unit 3731  
4/8/09

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
4/8/09